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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,797	11/18/2003	Steve Golden	CSI-2009C1	5178
33931 7590 04/19/2007 LAW OFFICE OF HARRY J. MACEY COURT HOUSE PLAZA, SUITE 410 260 SHERIDAN AVENUE PALO ALTO, CA 94306			EXAMINER WOO, JULIAN W	
			ART UNIT 3731	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/715,797	GOLDEN ET AL.	
	<b>Examiner</b> Julian W. Woo	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 February 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 1-63 and 82-122 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 64-76 is/are rejected.
- 7) Claim(s) 77-81 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/15/07</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group V, claims 64-81 in the reply filed on February 15, 2007 is acknowledged. The traversal is on the ground(s) that "there would be no significant burden on the PTO to search two or more...groups." This is not found persuasive because, as shown in the restriction requirement, the search and examination for at least one of the claimed inventions are not necessarily required for another of the claimed invention(s). The showing of significant burden was shown by the differing classes/subclasses for each of the inventions, where a search for at least one of the inventions, would not likely result in finding art pertinent to the other invention(s).

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 66 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Popov et al. (5,702,412). Popov et al. disclose, at least in figures 3-7 and in col. 6, line 30 to col. 9, line 47; a method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel (12), where the method includes forming an opening in the blood vessel (see fig. 5 or 7), inserting an occluding member (30 or 32) into the opening, anastomosing a graft (10) to the vessel, and fastening the walls of the graft and vessel together using fasteners (46, 48).

4. Claims 64-66, 69-71, 74, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al. (6,113,612). Swanson et al. disclose, at least in figures 7-11 and in col. 6, line 28 to col. 7, line 34 and col. 14, lines 31-45; a method for performing an anastomosis on a vessel wall, while maintaining blood flow within the vessel, where the method includes positioning a cannula (240) so that it extends through a vessel wall (300), attaching a graft (120) to the vessel wall adjacent to the cannula while the cannula extends through the vessel wall, and removing the cannula, where the cannula is positioned in the vessel wall from the interior of the vessel (via guidewire 210, which is in the interior of the vessel). The method also includes forming an opening in the blood vessel (see fig. 8), inserting an occluding member (110) into the opening, inserting the occluding member into the opening cut into the vessel while a cutting tool (220) is still in the opening, withdrawing the cutting tool (distally) to allow the occluding member to expand against the periphery of the opening (see fig. 10), placing the graft over the occluding member and in alignment with the opening prior to anastomosing (see figs. 8 and 9), and anastomosing the walls of the graft and vessel

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using fasteners (22 and 42), where the occluding member includes fasteners attached thereto, the method further including pulling back the occluding member slightly, after expanding to occlude, thereby piercing the vessel wall with needles (44) attached to the fasteners.

5. Claims 66-68, 72, and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by LeMole (5,893,369). LeMole discloses, at least in figures 5-8 and in col. 5, line 34 to col. 7, line 23; a method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel (12), where the method includes forming an opening in the blood vessel (see figs. 6 and 7), inserting an occluding member into the opening (38), anastomosing a graft (14) to the vessel, piercing the vessel wall with an anchor member (34), cutting the opening around the anchor member with a cutting tool (32), removing a tissue plug produced by the cutting prior to inserting an occluding member (see fig. 8), sliding a generally circular centering disk (30) along the anchor member onto the vessel wall prior to cutting and clamping vessel wall tissue between the centering disk and an end portion of the anchoring member, and removing the tissue plug in a clamped configuration between the centering disk and anchoring member.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popov et al. (5,702,412) in view of Ho et al. (6,514,265). Popov et al. disclose the invention substantially as claimed, but do not disclose fastening with self-closing fasteners. Ho et al. teach, at least in figures 2A –3G and in col. 5, line 62 to col. 6, line 13 and col. 8, lines 9-42, fastening the walls of a graft and a vessel together using self-closing fasteners (210). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ho et al., to modify the method of Popov et al., so that self-closing fasteners are applied for the fastening of a graft to a vessel. Such fasteners would allow a quick (as compared to the time for fastening with sutures or conventional clips), safe, and effective anastomosis of a graft and a vessel within the narrow confines of a surgical site.

***Allowable Subject Matter***

8. Claims 77-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses, a method from performing an anastomosis on a vessel wall, where the method includes, *inter alia*, inserting an occluding member into an opening cut into a vessel, and anastomosing a graft to the vessel at the opening, where the occluding member includes fasteners with attached needles attached to the occluding member, where the method further includes grasping the needles and pulling them entirely through the vessel wall; and where a cutting tool includes an adapter that retains needles, where the method includes inserting the cutting tool and adapter into the vessel and pulling back the adapter and cutting tool in order to pierce the vessel wall with the needles, and pulling the needles all the way through the vessel.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kaster et al. (5,234,447) teach a method of anastomosis.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner

April 17, 2007